§522.1192 Ivermectin injection.

(a) *Specifications*—(1) *Horses.* Each milliliter of solution contains 20 milligrams of ivermectin (2 percent).

(2) *Cattle, reindeer, swine, and American bison.* Each milliliter of solution contains 10 milligrams of ivermectin (1 percent).

(3) *Piglets 70 pounds or less and ranch-raised foxes.* Each milliliter of solution contains 2.7 milligrams of ivermectin (0.27 percent).

(b) *Sponsors.* See sponsors in §510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 050604 for use as in paragraph (d) of this section.

(2) No. 059130 for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section of this section.

(c) *Related tolerances.* See §556.344 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 20 milligrams per 100 kilograms (220 pounds) of body weight.

(ii) *Indications for use.* It is used in horses for the treatment and control of large strongyles (adult) (*Strongylus vulgaris, Strongylus edentatus, Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (*microfilariae*) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *Limitations.* For intramuscular use only. Do not use intravenously. Not for use in horses intended for food. Effects of this drug on pregnant mares have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—

(i) *Amount.* 200 micrograms per kilogram of body weight by subcutaneous injection.

(ii) *Indications for use*—For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); sucking lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mites (scabies) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For No. 059130 in §510.600(c) of this chapter: It is also used to control infections of *D. viviparus* for 28 days after treatment; *O. ostertagi* for 21 days after treatment; and *H. placei, T. axei, C. punctata, C. oncophora,* and *O. radiatum* for 14 days after treatment. For No. 050604 in §510.600(c) of this chapter: To control infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi, T. axei,* and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations.* Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Not for intravenous or intramuscular use. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(3) *Reindeer*—(i) *Amount.* 10 milligrams per 50 kilograms (110 pounds) body weight.

(ii) *Indications for use.* It is used in reindeer for treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations.* For subcutaneous use only. Not for intramuscular use. Do not treat reindeer within 56 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount.* 300 micrograms per kilogram (2.2 pounds).

(ii) *Indications for use.* It is used in swine for treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm,

Ascaris suum; red stomach worm, *Hyostrongylus rubidus;* nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *Strongyloides ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

(iii) *Limitations.* For subcutaneous injection in the neck of swine only. Do not treat swine within 18 days of slaughter. Do not use in other animal species as severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(5) *Ranch-raised foxes*—(i) *Amount.* 200 micrograms per kilogram body weight. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

(iii) *Limitations.* For subcutaneous use only. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(6) *American bison*—(i) *Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds) of body weight.

(ii) *Indications for use.* It is used in American bison for the treatment and control of grubs (*Hypoderma bovis*).

(iii) *Limitations.* For subcutaneous use. Do not slaughter within 56 days of last treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 5344, Feb. 13, 1984, as amended at 50 FR 30268, July 25, 1985; 51 FR 25686, July 16, 1986; 51 FR 27021, July 29, 1986; 51 FR 29463, Aug. 18, 1986; 53 FR 11064, Apr. 5, 1988; 56 FR 14020, Apr. 5, 1991; 60 FR 45041, Aug. 30, 1995; 62 FR 14634, Mar. 27, 1997; 62 FR 63271, Nov. 28, 1997; 63 FR 7702, Feb. 17, 1998; 64 FR 26671, May 17, 1999; 66 FR 13236, Mar. 5, 2001; 69 FR 53617, Sept. 2, 2004]

§ 522.1193 Ivermectin and clorsulon injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams (1 percent) of ivermectin and 100 milligrams (10 percent) of clorsulon.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.163 and 556.344 of this chapter.

(d) *Conditions of use*—(1) *Amount.* 1 milliliter (10 milligrams of ivermectin and 100 milligrams of clorsulon) per 50 kilograms (110 pounds).

(2) *Indications for use.* It is used in cattle for the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). It is also used to control infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi, T. axei,* and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997; 64 FR 26671, May 17, 1999; 69 FR 31735, June 7, 2004]

§ 522.1204 Kanamycin sulfate injection.

(a) *Specifications.* Each milliliter of kanamycin sulfate injection veterinary contains either 50 or 200 milligrams of kanamycin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.